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13		
	JONATHAN KANFER, on behalf of	Case No: 3:15-cv-00120-H-JLB
14	himself, all others similarly situated and the	
15	general public,	<u>CLASS ACTION</u>
16	Plaintiff,	FIRST AMENDED COMPLAINT FOR
17	Traintiff,	VIOLATIONS OF:
18	V.	• CALIFORNIA UNFAIR
19	PHARMACARE US, INC., a Delaware	COMPETITION LAW;
	Corporation,	• CALIFORNIA FALSE ADVERTISING LAW;
20		CALIFORNIA CONSUMERS
21	Defendant.	LEGAL REMEDIES ACT;
22		BREACH OF EXPRESS  WARDANITHES.
23		WARRANTIES; • BREACH OF IMPLIED
24		WARRANTIES;
25		• MAGNUSON-MOSS
		WARRANTY ACT;
26		
27		DEMAND FOR JURY TRIAL
28		

Kanfer v. PharmaCare US, Inc., No. 3:15-cv-00120-H-JLB FIRST AMENDED COMPLAINT

Plaintiff Jonathan Kanfer ("Plaintiff"), on behalf of himself, all others similarly situated, and the general public, by and through his undersigned counsel, hereby sues Defendant PharmaCare US, Inc. ("Defendant"), and alleges the following upon his own knowledge, or where he lacks personal knowledge, upon information and belief and the investigation of his counsel.

## I. <u>INTRODUCTION</u>

- 1. Defendant PharmaCare US, Inc. falsely markets, distributes, and sells an over-the-counter ("OTC") product called "IntenseX" (the "Product") as having beneficial health and aphrodisiac properties to increase "Sexual Power and Performance," despite that none of the ingredients in the Product, individually or in combination, provide such benefits.
- 2. Plaintiff Jonathan Kanfer read, believed, and relied upon Defendant's claims when purchasing the Product during the Class Period, defined herein, and was damaged as a result.
- 3. Plaintiff brings this action challenging Defendant's claims relating to IntenseX on behalf of himself, all others similarly situated, and the general public under California's Unfair Competition Law ("UCL"), False Advertising Law ("FAL"), and Consumers Legal Remedies Act ("CLRA"), California's express and implied warranty provisions, and the Magnuson-Moss Warranty Act ("MMWA").
- 4. Plaintiff seeks in equity an order compelling PharmaCare US, Inc. to (1) cease marketing IntenseX using the misleading tactics complained of herein, (2) conduct a corrective advertising campaign, (3) restore the amounts by which Defendant has been unjustly enriched, and to (4) destroy all misleading and deceptive materials.
- 5. Plaintiff further seeks actual and punitive damages, pre and post-judgment interest, attorneys' fees, costs, and such other and further relief as this Court may deem just, equitable, or proper.

## II. JURISDICTION & VENUE

6. The Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), the Class Action Fairness Act ("CAFA"), because the matter in controversy exceeds the sum or

- 7. Defendant manufactures, markets, and sells the Product from within California to consumers in every state in the United States. Personal jurisdiction is derived from the fact that Defendant conducts substantial business within the State of California and within this judicial District.
- 8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, as all marketing and advertising decisions relating to the IntenseX Product occurs within the County of San Diego and within this judicial District. Moreover, Defendant resides in this District; is authorized to conduct business in this District and does conduct substantial business in this District; has intentionally availed itself of the laws and markets of this District through the promotion, marketing, distribution, and sale of the Product in this District; is subject to personal jurisdiction in this District; and a related case is currently pending in this District. *See Sandoval v. PharmaCare US, Inc.*, No. 3:15-cv-00738-H-JLB (S.D. Cal.). In addition, the packaging for the IntenseX Product states: "Dist. By: PharmaCare US, Inc. San Diego, CA 92112."
- 9. Additionally, Defendant's subsidiary, Real Health Laboratories, is located in San Diego, California and is responsible for the sale and marketing of IntenseX.

## III. PARTIES

- 10. Plaintiff Jonathan Kanfer is a resident of West Palm Beach, Florida who repeatedly purchased the Product for personal and/or household consumption.
- 11. Defendant PharmaCare US, Inc. is Delaware corporation with its principal place of business located at 101 Montgomery Street, Suite 2050, San Francisco, California 94104. Defendant also operates out of a San Diego office, and promotes IntenseX using inperson marketing at San Diego events such as Street Scene music festival.
  - 12. Defendant PharmaCare US, Inc. is registered to do business in California as

entity number C3217079. Defendant is a leading manufacturer, distributor, and marketer of various natural health products and supplements. Defendant markets its products under a variety of brand names, including "Sambucol," "Skin Doctors," and "Real Health Laboratories." The IntenseX product is sold and marketed under Defendant's "Real Health Laboratories" brand. In the "contact us" sections of the PharmaCare US, Inc. website, the Real Health Laboratories website, and the IntenseX website, Defendant's contact address is listed as PO Box 122950 San Diego, California 92112-2950. In addition, the contact phone number has a San Diego area code—(858) 997-1156. All marketing and advertising decisions relating to the IntenseX Product occur within the County of San Diego and within this judicial District.

13. Members of the Class reside in California and each of the other 49 states of the United States, with two-thirds or more than two-thirds of the Class residing outside the State of California.

### IV. FACTUAL ALLEGATIONS

- 14. Defendant has distributed, marketed, and sold the IntenseX product on a nationwide basis, both online and at retail store locations.
- 15. IntenseX is available in a bottle of 20 tablets and retails for approximately \$9.99.
- 16. Defendant prominently labels its product under the name "IntenseX" implying that the Product's ingredients will enable "intense sex" despite that the Product is not effective as an aphrodisiac.
- 17. Defendant further claims that the IntenseX Product increases "Sexual Power and Performance," and that "IntenseX is designed to intensify your endurance, stamina and sexual performance." The Product's label further states that the "fast acting formula quickly dissolves in the body releasing an energy packed blend of potent herbal extracts" and that with the Product a user can "[a]chieve peak performance to maximize the experience when you want it most." Additionally, the label claims that the Product is "laboratory quality tested," contains a "proprietary stamina blend," and is "produced using

the highest manufacturing standards." These labeling claims are false and misleading for the reasons described herein.



## A. The Composition of IntenseX

18. IntenseX consists of a blend of small amounts of extracts from herbs, roots, and other organic substances, some of which are purported to have an effect on the human body.

19. The figure below shows the ingredients in IntenseX:

Supplement Fac	ts			
and the second of the first of the second of	Servings Per Co	ntainer: 10		
Amount Per Serving	%D	ally Value		
Calcium (as calcium carbonate)	575 mg	58%		
Guarana, 6:1 Extract, containing 88 mg caffeine	244.0	100		
(Paullinia cupana) (seed)	400 mg	†		
Muira Puama, 4:1 Extract (Ptychopelatum olacoides)(root	) 250 mg	†		
Catuaba, 4:1 Extract (Erythroxylum catuaba)(bark)	250 mg	†		
Ginkgo Biloba 24/6% Extract (leaf)	40 mg	1		
PROPRIETARY STAMINA BLEND	200 mg	+		
Avena Sativa (herb), Cordyceps (Cordyceps sinensis	)			
Ashwaganda (Withania somnifera)(root)				
PROPRIETARY ENERGY BLEND	100 mg	†		
Tribulus Terrestris 40% Extract (herb), American Ginseng 5% Extract				
(Panax quinquefolium)(root), Korean Ginseng 7% Extract (Panax ginseng)(root				
PROPRIETARY WARMING BLEND	200 mg	†		
Ginger (Zingiber officinale) (bark), Cinnamon (Cinnam	nomum casia) (b	ark)		
Nutmeg (Myristica fragrans) (seed), Cayenne (Capsic	um annuum) (fri	Jit)		
† Percent Daily Values have not been established.		V.1		
Other ingredients: Microcrystalline cellulose, stearic acid, silicon dioxide, magnesium stearate, and clear coating. Storage: Product should be stored in a cool, dry place, awa				
These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.				

- 20. IntenseX, by means of its ingredients, claims to increase "Sexual Power & Performance" and suggests to consumers that it is effective as an aphrodisiac drug product.
- 21. This, however, is false and/or misleading because none of the ingredients in IntenseX, individually or in combination, increase male strength and performance or are effective as an aphrodisiac.
- 22. Some of the ingredients in IntenseX include Catuaba, Avena Sativa, Muira Puama, Ginseng, Ginkgo Biloba, and Tribulus Terrestris.
- 23. According to the New York University's Langone Medical Center, "there is as yet no real evidence that [Catuaba, Avena Sativa, Muira Puama, and Tribulus Terrestris] offer any benefits" for increasing sexual performance or desire. Moreover, the Langone Medical Center has noted that there are no reliable scientific studies (such as double-blind, placebo controlled studies) to establish that Ginkgo Biloba—another ingredient in

<sup>&</sup>lt;sup>1</sup> See http://www.med.nyu.edu/content?ChunkIID=21720 (last visited Jan. 5, 2015).

IntenseX—improves sexual function. In fact, at least two studies have shown that "ginkgo failed to improve sexual function to any greater extent than placebo."<sup>2</sup>

- Ginkgo Biloba has been proven to be ineffective in improving sexual function.<sup>3</sup> 24.
- "[E]vidence supporting a role for muira puama in sexual health is very 25. limited," and "its wide-spread use in supplements for sexual health is not supported."
- "Not only has an effect of tribulus [terrestris] on human sexual response not 26. been well-documented, but guidelines and dosages are not clear." Therefore, "the reason for [its] inclusion [in supplements purporting to provide sexual benefits] is, at this time, not strongly supported on the basis of scientific evidence."5
- 27. According to the University of Maryland Medical Center, "Asian ginseng is widely believed to boost sexual performance, but there aren't many studies to back this up." Although one South Korean study concluded that "oral administration of [ginseng] extract improved all domains of sexual function," the research authors "neglect to mention that in all domains, barring premature ejaculation, this improvement was no better than taking a dummy placebo pill."8 In fact, "[t]he study actually found that ginseng did not improve sexual dysfunction more than placebo across the vast majority of areas tested, which included: erectile function, intercourse satisfaction, orgasmic function, sexual desire,

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<sup>&</sup>lt;sup>2</sup> See id.

<sup>&</sup>lt;sup>3</sup> Kang, B. et al. A placebo-controlled double blind trial of Ginkgo Biloba for antidepressant induce sexual dysfunction. 17 Human Physcopharmacology: Clinical and Experimental 279-284 (2002).

<sup>&</sup>lt;sup>4</sup> Rowland, D. et al. *Plant-Derivatives and Herbs Used for the Promotion of Sexual Health* and the Treatment of Sexual Problems. 18 Annual Review of Sex Research 225-257 (2007). <sup>5</sup> *Id*.

http://umm.edu/health/medical-reference-guide/complementary-and-alternative-medicineguide/herb/asian-ginseng (last visited June 18, 2015).

Choi YD, Park CW, Jang J, et al. Effects of Korean ginseng berry extract on sexual function in men with erectile dysfunction: a multicenter, placebo-controlled, double-blind clinical study. International Journal of Impotence Research. Published online November 26 2012.

<sup>&</sup>lt;sup>8</sup> http://www.nhs.uk/news/2013/01January/Pages/Ginseng%E2%80%93the-new-Viagra.aspx (last visited June 18, 2015).

and overall sexual satisfaction."9

- 28. Avena Sativa, Guarana, Ginger, Nutmeg, Cinnamon, and Cayenne also do not improve human sexual function.
- 29. While a few unreplicated scientific studies suggest ingredients in the Product may, in necessary amounts, have benefits to individuals suffering certain specific conditions, many of the ingredients in the Products appear to have never been studied at all or have not otherwise been shown to have any effect on the human body, much less to increase sexual power and performance.
- 30. In any case, the FDA has proclaimed that "[t]here is a lack of adequate data to establish general recognition of the safety and effectiveness of any of these ingredients [i.e. ginseng and Korean ginseng] or *any* other ingredient, for OTC use as an aphrodisiac." 21 C.F.R. § 310.528(a) (emphasis added).
- 31. Further, consuming random herbs and herbal extracts presents a risk of an allergic or other adverse reaction without any offsetting benefit.

## **B.** Specific Misrepresentations and Deceptive Acts

- 32. **Misleading supplement name:** Defendant prominently labels its product under the name "IntenseX,"—phonetically identical to "intense sex"—falsely implying it is an aphrodisiac.
- 33. **Misleading heading:** Displayed at the top of the Product's front label are the words "Fast Acting!" which misleadingly implies purchasers will receive a benefit quickly. However, the Product provides no benefit, sexual or otherwise, quickly or slowly.
- 34. **Misleading sub-heading:** The front of the Product's label features the misleading sub-heading "Sexual Power & Performance" despite that the Product fails to improve human sexual power and there is no evidence it contributes to human sexual performance.
  - 35. **Misleading claim:** The labeling of the Product claims "IntenseX is designed to

<sup>9</sup> *Id*.

to intensify your endurance, stamina and sexual performance" despite that the Product fails to intensify or enhance endurance, stamina, or sexual performance.

- 36. **Misleading claim:** The labeling of the Product claims "This fast acting formula quickly dissolves in the body releasing an energy packed blend of potent herbal extracts" suggesting that the Product provides a benefit quickly, however, it fails to provide any benefit.
- 37. **Misleading claim:** The labeling of the Product states "Achieve peak performance to maximize the experience when you want it most" suggesting the Product will improve your sexual performance or experience despite having no effect on human sexual performance or experience.
- 38. **Misleading claim:** The labeling of the Product claims it is "Laboratory Quality Tested." This statement implies that the Product has passed and met laboratory tests and standards that support its claims, when in fact the Product does not work as advertised. This claim is false. Defendant never conducted proper controlled studies on the effectiveness of IntenseX.
- 39. **Misleading claim:** The labeling of the Product claims it is a "Proprietary Stamina Blend." This statement implies that the ingredients which constitute the Product have been chosen based on scientific research in order to increase stamina. In fact, none of the ingredients in the Product, individually or in combination, increase stamina.
- 40. **Misleading claim:** The labeling of the Product claims it is "Produced using the the highest manufacturing standards." This statement implies that the Product met standards that support its claims, when in fact the Product does not work as advertised.
- 41. **Misleading claim:** The labeling of the Product contains directions for "Recommended Use" that states "recommended use is one to two tablets 30-60 minutes before benefit is desired." This statement implies that the Product is efficacious and provides real benefits within a specific amount of time. The Product, however, does not provide any benefit, nor does it do so within the specified time period.

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- 42. **Misleading claim:** On the Product's website, <sup>10</sup> Defendant provides the following claim for its "Asian Ginseng" ingredient: "Use if you suffer from coldness, rheumatism, colds and flu, frigidity and impotence." Ginseng's effect on sex, however, has been extensively studied, and it has been proved to have no effect in improving sexual ability or remedying "frigidity and impotence."
- 43. **Misleading claim:** With regard to Tribulus terrestris, misspelled on its website as "Tribulus terestris," Defendant claims, "Empirical evidence suggests that tribulus may help impotence in men and diminished libido in both sexes." In fact, this is false, as no such evidence exists. While the herb has been studied, scientists concluded it was not effective.

## C. <u>IntenseX is a Misbranded Drug</u>

- 44. The labeling described above, including but not limited to "IntenseX," "Sexual Power & Performance," and "IntenseX is designed to intensify your endurance, stamina and sexual performance," alone and in context with other labeling claims and packaging graphics, evidence the Product's intended use as a purported aphrodisiac, to arouse or increase sexual desire or energy, or improve sexual performance.
- 45. Pursuant to Title 21 of the Code of Federal Regulations, Part 310.528 (21 CFR § 310.528) any OTC drug product that is labeled, represented, or promoted for use as an aphrodisiac, like IntenseX, is regarded as a "new drug" within the meaning of section 201(p) of the FDCA (located at 21 U.S.C. § 355(p)).
- 46. The FDCA requires any new drug to have an application approved by the Food and Drug Administration ("FDA") before the drug can be marketed to the public, and further that the drug's label be approved by the FDA prior to marketing or selling the drug to the public. *See*, *generally*, *id.*; 21 U.S.C. §§ 355(a), (b) [New Drug Application], (j)

<sup>&</sup>lt;sup>10</sup> IntenseX's packaging instructs purchasers who have questions or comments to visit its website (www.intensex.com).

<sup>&</sup>lt;sup>11</sup> www.intensex.com/ingredients.asp (last visited June 18, 2015).

<sup>&</sup>lt;sup>12</sup> *Id*.

[Abbreviated New Drug Application, for generic drugs].

- 47. Defendant's Product violates Section 505(a) of the FDCA since the adequacy of the labeled directions for its "aphrodisiac" uses has not been approved by the FDA prior to the Product being marketed to the public (*see* 21 U.S.C. § 355(a)).<sup>13</sup> Accordingly, the Product is misbranded under section 502(f)(1) of the FDCA (located at 21 U.S.C. § 352).
- 48. Further, IntenseX includes the ingredients: Ginseng, Muira Puma, and Catuaba. The FDA has specifically found these are not safe and effective for OTC use as an aphrodisiac. 21 C.F.R. § 310.528. The FDA bars these label claims, which are false, misleading, and unsupported by scientific data. *Id.* Thus, based on the evidence currently available, any OTC drug products containing ingredients for use as an aphrodisiac, including IntenseX, cannot be generally recognized as safe and effective, and instead are misbranded new drugs. *See id.*
- 49. Although Defendant labels its IntenseX Product as a dietary supplement, the Product is really a misbranded aphrodisiac drug product. Specifically, federal regulations prohibit Defendant from making "disease claims" on dietary supplements. *See* 21 C.F.R. § 101.93. Disease claims are generally described as statements which claim to diagnose, mitigate, treat, cure or prevent disease where the statements claim "explicitly or implicitly, that the product . . . has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology." *Id.* The labeling of IntenseX leads reasonably prudent consumers into believing that the Product can treat or cure impotence, premature ejaculation, erectile dysfunction, and diminished libido, which are diseases recognized by the FDA.
- 50. In addition, Defendant violates 21 U.S.C. 343(r)(6), which requires, among other things, that all structure function claims are truthful and not misleading, based on competent scientific evidence, and prominently provide a specified disclaimer explaining that the FDA has not evaluated the structure function claim. *See also* Cal. Health & Safety

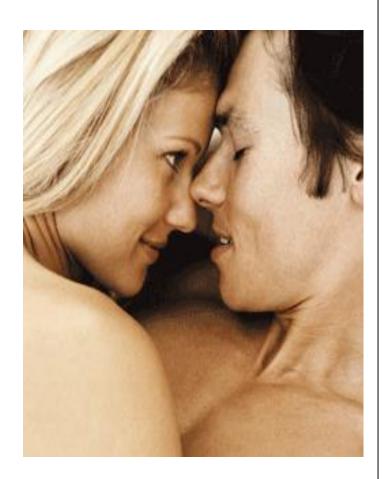
<sup>&</sup>lt;sup>13</sup> In addition to proving effectiveness, the manufacturer of a new drug must also prove the drug's safety, sufficient to meet FDA standards. 21 U.S.C. § 355(d).

Code § 110670 (incorporating requirements of 21 U.S.C. § 343(r)(6)).

- 51. California Health and Safety Code, Division 104, Part 5, contains the Sherman, Food, Drug, and Cosmetic Law ("Sherman Law"). Cal. Health & Safety Code §§ 109875-111915. The Sherman Law imposes identical requirements to the federal FDCA: "All nonprescription drug regulations and regulations for new drug applications under the FDCA are the regulations of this State." Cal. Health & Safety Code §§ 110110-110111, 110115. The Sherman Law also defines a "drug" as "any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal." Cal. Health & Safety Code § 109925(c).
- 52. In effect, the Sherman Law requires that Federal Law is followed, and where it is not, such a violation of Federal law also violates the Sherman Law.
- 53. The Sherman Law is explicitly authorized by the FDCA because it imposes identical requirements. 21 U.S.C. § 343-1.
  - 54. IntenseX's packaging refers consumers to the Product's website.<sup>14</sup>
- 55. Misleading representations on the Product's website render it an unapproved aphrodisiac drug within the meaning of 21 C.F.R. § 310.528.

<sup>&</sup>lt;sup>14</sup> www.intensex.com





## FAST ACTING FORMULA

IntenseX<sup>TM</sup> is the only fast-acting formula that works within minutes to give you the powerful, sexual energy you need to make a 'long lasting' impression.

IntenseX<sup>TM</sup> was formulated to rev up your sex drive and enhance stamina, endurance and most importantly, heighten and complete your sexual experience.

- 56. Specifically, Defendant's website claims the Product "WORKS SO FAST YOU MAY NOT MAKE IT HOME" and that its "FAST ACTING FORMULA" "is the only formula that works within minutes giving you the powerful energy you need to make a 'long lasting' impression." Additionally, the website claims "IntenseX was formulated to rev up your sex drive and enhance stamina, endurance, and most importantly, heighten and complete your sexual experience."
- 57. IntenseX's marketing images, *supra*, further show IntenseX is marketed and intended to be used as an aphrodisiac.

<sup>15</sup> www.intensex.com (last visited June 18, 2015)

<sup>&</sup>lt;sup>16</sup> *Id*.

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- 58. Furthermore, the Product's website touts IntenseX's ingredients aphrodisiacs, effective for the treatment of frigidity, impotence, sexual dysfunction, and diminished libido.<sup>17</sup>
- 59. These claims, alone, and even more so in combination with each other, and more still in combination with the label claims, unlawfully represent that IntenseX is an aphrodisiac.
- 60. Because IntenseX has not been approved as a new drug, it is an unlawful and misbranded unapproved aphrodisiac drug under 21 C.F.R. § 310.528.
- 61. Plaintiff and Members of the Class would not have purchased IntenseX if it were known to them that the Product is misbranded pursuant to California's Sherman Law and FDA regulations.

#### V. **RELIANCE AND INJURY**

- Mr. Kanfer purchased the IntenseX Product on at least four occasions from a 62. Publix Market store near his home in West Palm Beach, Florida for approximately \$9.99. Plaintiff first purchased the Product in or around October of 2013 and continued to purchase the Product until approximately January of 2014.
- When purchasing IntenseX, Mr. Kanfer and the Class were seeking a product 63. that had the aphrodisiac qualities promised on the Product's label, namely, a high quality and effective aphrodisiac that enhances male performance.
- When deciding to purchase IntenseX, Plaintiff and the Class read and relied on 64. the following deceptive claims contained on the packaging of IntenseX. These statements were made by Defendant directly on the packaging of IntenseX at the time Plaintiff purchased IntenseX:
  - a. the Product's name, "IntenseX"
  - b. "Sexual Power and Performance"
  - c. "IntenseX is designed to intensify your endurance, stamina and sexual

<sup>&</sup>lt;sup>17</sup> www.intensex.com/ingredients.asp (last visited June 18, 2015).

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performance"

- d. "This fast acting formula quickly dissolves in the body releasing an energy packed blend of potent herbal extracts"
- e. "Achieve peak performance to maximize the experience when you want it most"
- f. "Laboratory Quality Tested"
- g. "Proprietary Stamina Blend"
- h. "Produced using the highest manufacturing standards"
- i. "100% Satisfaction Guaranteed"
- 65. Based on these representations, Plaintiff believed IntenseX had powerful aphrodisiac qualities and would improve his sexual power and performance.
- 66. Plaintiff believed IntenseX had the qualities he sought based on these deceptive labeling claims, but the Product was actually unsatisfactory to Plaintiff for the reasons described herein, *i.e.*, the Product did not deliver the purported benefits, there is no evidence the ingredients in IntenseX provide the claimed benefits, and the consumption of IntenseX is potentially dangerous, which is an unfair and unreasonable risk considering it provides no benefits.
- 67. IntenseX costs more than similar products without misleading labeling, and would have cost less absent the false and misleading statements.
- 68. Plaintiff would not have been willing to purchase the Product absent its false and misleading claims. Nor would he have purchased the Product had he known it is misbranded under California and Federal law.
- 69. For these reasons, IntenseX was worth far less than what Plaintiff and the Class paid for it. In fact, IntenseX has no value and should not be consumed by anyone.
- 70. Instead of receiving a product that had actual and substantiated healthful or other beneficial qualities, the Product Plaintiff and the Class received was one which does not provide the claimed benefits.
  - 71. Plaintiff and the Class lost money as a result of Defendant's deceptive claims

and practices in that they did not receive what they paid for when purchasing IntenseX.

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- 72. Plaintiff and the Class altered their position to their detriment and suffered damages in an amount equal to the amount they paid for the Product.
- 73. The senior officers and directors of Defendant allowed IntenseX to be sold with full knowledge or reckless disregard that the challenged claims are fraudulent, unlawful, and misleading.

### VI. <u>CLASS ACTION ALLEGATIONS</u>

74. Plaintiff brings this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of himself and all others similarly situated. Plaintiff seeks to represent a Nationwide Class, defined as:

All persons in the United States (excluding officers, directors, and employees of Defendant) who purchased IntenseX primarily for personal, family, or household use, and not for resale since January 1, 2004.

- 75. The Members in the proposed Class are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of all Class Members in a single action will provide substantial benefits to the parties and the Court.
- 76. Questions of law and fact common to Plaintiff and the Class include, but are not limited to:
  - a. whether Defendant contributed to, committed, and/or is responsible for the conduct alleged herein;
  - b. whether Defendant's conduct constitutes the violations of law alleged herein;
  - c. whether Defendant acted willfully, recklessly, negligently, or with gross negligence in the violations of law alleged herein; and
  - d. whether Class Members are entitled to compensatory, injunctive, and other equitable relief;
  - 77. Plaintiff's claims are typical of Class Members' claims in that they are based

on the same underlying facts, events, and circumstances relating to Defendant's conduct.

- 78. Absent Defendant's deceptive claims, Plaintiff and the Class Members would not have purchased IntenseX.
- 79. Plaintiff will fairly and adequately represent and protect the interests of the Class, has no interests incompatible with the interests of the Class, and has retained counsel competent and experienced in class action litigation.
- 80. The Class is sufficiently numerous, as the Class contains at least hundreds of thousands of members who purchased IntenseX across the United States.
- 81. Class treatment is superior to other options for resolution of the controversy because the relief sought for each Class Member is small such that, absent representative litigation, it would be infeasible for Class Members to redress the wrongs done to them.
- 82. Questions of law and fact common to the Class predominate over any questions affecting only individual Class Members.
- 83. Defendant has acted on grounds applicable to the Class, thereby making appropriate final injunctive and declaratory relief concerning the Class as a whole.
- 84. Class treatment is appropriate under Fed. R. Civ. P. 23(a) and both Fed. R. Civ. P. 23(b)(2) and 23(b)(3). Plaintiff does not contemplate class notice if the Class is certified under Fed. R. Civ. P. 23(b)(2), which does not require notice. Plaintiff contemplates notice via publication if the Class is certified under Fed. R. Civ. P. 23(b)(3) or if the Court determines class notice is required notwithstanding that notice is not required under Fed. R. Civ. P. 23(b)(2). Plaintiff will, if notice is required, confer with Defendant and seek to present the Court with a stipulation and proposed order on the details of a class notice plan.

## VII. <u>CAUSES OF ACTION</u> FIRST CAUSE OF ACTION

## California's Unfair Competition Law, Unlawful Prong Cal. Bus. & Prof. Code §§ 17200 et seq.

85. Plaintiff realleges and incorporates the allegations elsewhere in this Complaint as if set forth in full herein, and further alleges as follows:

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- 86. California Business and Professions Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."
- 87. The business practices and omissions, misrepresentations, and non-disclosures of Defendant as alleged herein constitute "unlawful" business acts and practices in that Defendant's conduct violates California's False Advertising Law, Consumers Legal Remedies Act, and breaches California's express and implied warranty provisions and the Magnuson-Moss Warranty Act.
- 88. Defendant's conduct is further "unlawful" because it violates the FDCA and its implementing regulations in the following ways:
  - Defendant's deceptive statements violate 21 U.S.C. §§ 343(a) and 352, a. which deem a food or drug (including nutritional supplements) misbranded when the label contains a statement that is "false or misleading in any particular";
  - Defendant's deceptive statements are per se false and misleading b. because the FDA has ruled there is a lack of adequate data to establish general recognition of the safety and effectiveness of any of the ingredients in IntenseX, or any other ingredient, for OTC use as an aphrodisiac; and labeling claims for aphrodisiacs for OTC use are "either false, misleading, or unsupported by scientific data." 21 C.F.R. § 310.528(a);
  - Defendant's deceptive statements violate 21 C.F.R § 310.528(b), which c. mandates that any OTC product that is labeled, represented, or promoted for use as an aphrodisiac, like IntenseX, is regarded as a "new drug" within the meaning of 21 U.S.C. § 355(p), but Defendant does not have new drug approval for IntenseX or its labeling, as required under the FDCA and its implementing regulations. Accordingly, Defendant's Product is misbranded under section 502(f)(1) of the FDCA;
  - d. Defendant violates 21 C.F.R. § 101.93 because IntenseX's labeling leads

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- reasonable consumers to believe that the Product can treat or cure maladies, including premature ejaculation, impotence, erectile dysfunction, and diminished libido;
- e. Defendant's Product also violates the FDCA because, as an unapproved new drug and aphrodisiac, IntenseX is not generally recognized as safe and effective in the absence of a new drug application as set forth in the FDCA and its implementing regulations. 21 C.F.R. § 310.528(a).
- 89. Defendant's conduct is further "unlawful" because it violates the California Sherman Food, Drug, and Cosmetic Law, *see* Cal. Health & Safety Code §§ 109875-111900, which incorporates the provisions of the FDCA. *See id.* §§ 110110-110115.
- 90. Defendant profited from its sales of the falsely, deceptively, or unlawfully advertised Product to unwary consumers.
- 91. In accordance with Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unlawful, unfair, and fraudulent acts and practices, and to commence a corrective advertising campaign.
- 92. Plaintiff also seeks an order for the disgorgement and restitution of all monies from the sale of the Product, which were acquired through its unlawful acts of unfair competition.

## **SECOND CAUSE OF ACTION**

## California's Unfair Competition Law, Unfair and Fraudulent Prongs Cal. Bus. & Prof. Code §§ 17200 et seq.

- 93. Plaintiff realleges and incorporates the allegations elsewhere in this Complaint as if set forth in full herein, and further alleges as follows:
- 94. California Business and Professions Code § 17200 prohibits any "unlawful, unfair or fraudulent business act or practice."
- 95. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein also constitute "unfair" business acts and practices under the UCL in that Defendant's conduct is immoral, unethical, unscrupulous, or substantially

injurious to consumers, offends public policy by seeking to profit from consumers' vulnerability to false or deceptive virility or aphrodisiac claims, and the utility of their conduct, if any, does not outweigh the gravity of the harm to Defendant's victims.

- 96. The acts, omissions, misrepresentations, practices, and non-disclosures of Defendant as alleged herein constitute "fraudulent" business acts and practices under the UCL in that Defendant's claims are false, misleading, and have a tendency to, and did, deceive the Class and the general public, as detailed herein.
- 97. Defendant profited from its sales of the fraudulently, falsely and deceptively advertised Product to unwary consumers.
- 98. In accordance with Cal. Bus. & Prof. Code § 17203, Plaintiff seeks an order enjoining Defendant from continuing to conduct business through unfair and fraudulent acts and practices, and to commence a corrective advertising campaign.
- 99. Plaintiff further seeks an order for the disgorgement and restitution of all monies earned from the sale of the Product, which were acquired through acts of unfair, and fraudulent competition by Defendant.

## **THIRD CAUSE OF ACTION**

# California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500 et seq.

- 100. Plaintiff realleges and incorporates the allegations elsewhere in this Complaint as if set forth in full herein, and further alleges as follows:
- 101. In violation of California Business and Professions Code §§ 17500 *et seq.*, the advertisements, labeling, policies, acts, and practices described herein were designed to, and did, result in the purchase and use of IntenseX.
- 102. Defendant knew and reasonably should have known that the labeling claims on the Product were untrue or misleading.
- 103. Defendant profited from its sale of the falsely and deceptively advertised Product to unwary consumers.
  - 104. As a result, Plaintiff, the Class, and the general public are entitled to injunctive

and equitable relief, restitution, and an order for the disgorgement of the funds by which Defendant was unjustly enriched.

## **FOURTH CAUSE OF ACTION**

## California's Consumers Legal Remedies Act,

Cal. Civ. Code §§ 1750, et seq.

- 105. Plaintiff realleges and incorporates the allegations elsewhere in this Complaint as if set forth in full herein, and further alleges as follows:
- 106. California's Consumers Legal Remedies Act ("CLRA") prohibits deceptive practices in connection with the conduct of a business that provides goods, property, or services primarily for personal, family, or household purposes.
- 107. Defendant's false and misleading labeling and other policies, acts, and practices were designed to, and did, induce the purchase and use of Defendant's Product for personal, family, or household purposes by Plaintiff and Class Members, and violated and continue to violate the following sections of the CLRA:
  - a. § 1770(a)(5): representing that goods have characteristics, uses, or benefits which they do not have;
  - b. § 1770(a)(7): representing that goods are of a particular standard, quality, or grade if they are of another;
  - c. § 1770(a)(9): advertising goods with intent not to sell them as advertised; and
  - d. § 1770(a)(16): representing the subject of a transaction has been supplied in accordance with a previous representation when it has not.
- 108. Defendant profited from its sale of the falsely, deceptively, and unlawfully advertised Product to unwary consumers.
- 109. As a result, Plaintiff and the Class have suffered irreparable harm; and seek restitution and actual damages in the amount of the total retail sales price of the Product sold throughout the Class period to all Class Members, punitive damages in an amount sufficient to deter and punish, injunctive relief in the form of modified advertising and a

- 110. Pursuant to California Civil Code § 1780(d), Plaintiff has attached a "Venue Affidavit" hereto as **Exhibit 1**.
- 111. Pursuant to California Civil Code § 1782, on January 5, 2015, Plaintiff notified Defendant in writing by certified mail of the particular violations of § 1770 of the Act as to the Product and demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. Plaintiff's CLRA letter and certified mail receipts are attached hereto as **Exhibit 2**.
- 112. Defendant's wrongful business practices regarding the Product constituted, and constitute, a continuing course of conduct in violation of the CLRA since Defendant is still representing that the Product has characteristics, uses, benefits, and abilities which are false and misleading, and have injured Plaintiff and the Class.
- 113. As Defendant failed to implement remedial measures, Plaintiff and the Class seek injunctive relief under Civil Code § 1782(d), enjoining the above described wrongful conduct by Defendant, as well as actual and punitive damages for their CLRA claims, and attorneys' fees and costs.

## **FIFTH CAUSE OF ACTION**

## **Breach of Express Warranty**

- 114. Plaintiff realleges and incorporates the allegations elsewhere in this Complaint as if set forth in full herein, and further alleges as follows:
- 115. On the Product's label and through Defendant's marketing campaign as described above, Defendant made affirmations of fact or promises, or description of goods, which formed "part of the basis of the bargain" at the time of purchase in that Plaintiff and the Class purchased the Product in reasonable reliance on those affirmations. Cal. Com. Code § 2313(1). Those affirmations of fact or promises, or descriptions of the goods are fully described in ¶¶ 16-17, 32-43, and 64 of this Complaint.
  - 116. Defendant breached its express warranties with Plaintiff and the Class by

selling a Product which did not and cannot provide the benefits described above.

117. As a result of Defendant's breach of its warranties, Plaintiff and the Class were damaged in the amount of the purchase price of the Product.

### **SIXTH CAUSE OF ACTION**

## **Breach of Implied Warranty of Merchantability**

- 118. Plaintiff realleges and incorporates the allegations elsewhere in this Complaint as if set forth in full herein, and further alleges as follows:
- 119. Defendant through its acts and omissions set forth herein, in the sale, marketing and promotion of the Product, made representations to Plaintiff and the Class, on the Product's label, that the Product provides certain claimed benefits or properties that in essence increase "Sexual Power and Performance." Those representations are fully described in ¶¶ 16-17, 32-43, and 64 of this Complaint.
- 120. Plaintiff and the Class bought the Product manufactured, advertised, and sold by Defendant, as described herein.
- 121. Defendant is a merchant with respect to the goods of this kind which were sold to Plaintiff and the Class, and there was in the sale to Plaintiff and other Members of the Class an implied warranty that those goods were merchantable.
- 122. Defendant breached that implied warranty, however, in that the Product did and does not provide the purported benefits, as set forth in detail herein.
- 123. As an actual and proximate result of Defendant's conduct, Plaintiff and the Class did not receive goods as impliedly warranted by Defendant to be merchantable in that they did not conform to the promises and affirmations made on the container or label of the goods.
- 124. Plaintiff and Class have sustained damages as a proximate result of the foregoing breach of implied warranty in the amount of the Product's purchase price.

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### **SEVENTH CAUSE OF ACTION**

## Violation of the Magnuson-Moss Warranty Act 15 U.S.C. §§ 2301, et seq.

- 125. Plaintiff realleges and incorporates the allegations elsewhere in this Complaint as if set forth in full herein, and further alleges as follows:
- 126. Plaintiff brings this cause of action individually and on behalf of the Members of the Class against Defendant.
- 127. Plaintiff and the Class assert all state law warranty claims arising under the laws of the State of California, as allowed under section 2310(d) of the Magnuson-Moss Warranty Act ("MMWA").
- 128. Defendant's Product is a consumer product as defined in 15 U.S.C. § 2301(1), which costs more than \$5.00.
- 129. Plaintiff purchased the IntenseX product on multiple occasions and paid more than \$25.00 for his combined purchases of the IntenseX product.
  - 130. Plaintiff and Class Members are consumers as defined in 15 U.S.C. § 2301(3).
- 131. Defendant is a supplier and warrantor as defined in 15 U.S.C. §§ 2301(4), (5). In connection with the sale of the Product, Defendant issued written warranties as defined in 15 U.S.C. § 2301(6)(A), by making representations regarding the Product's efficacy. These statements are listed at ¶¶ 16-17, 32-43, and 64 of this Complaint (the "Express Warranties").
- 132. In fact, the Product does not conform to the Express Warranties because the Express Warranties are false and/or deceptive, whereby Defendant breached the Express Warranties made to Plaintiff and the Class.
- 133. Plaintiff and Class Members were injured as a direct and proximate result of Defendant's breach because they would not have purchased the Product absent the Express Warranties, which formed part of the basis of the bargain.
- 134. By reason of Defendant's breach of warranties, Defendant violated the statutory rights due to Plaintiff and Class Members pursuant to the Magnuson-Moss

Warranty Act, 15 U.S.C. §§ 2301 et seq., thereby damaging Plaintiff and Class Members.

135. Plaintiff and the Class seek damages, equitable relief, and attorney's fees and costs pursuant to 15 U.S.C. §§ 2310(d)(1), (2).

#### VIII. PRAYER FOR RELIEF

- 129. WHEREFORE, Plaintiff, on behalf of himself, all others similarly situated, and the general public, prays for judgment against Defendant as follows:
  - A. An order confirming that this class action is properly maintainable as a nationwide class action as defined above, appointing Plaintiff Jonathan Kanfer and his undersigned counsel to represent the Class, and requiring Defendant to bear the cost of class notice;
  - B. An Order compelling Defendant to conduct a corrective advertising campaign;
  - C. An Order requiring Defendant to disgorge all monies, revenues, and profits obtained by means of any wrongful act or practice;
  - D. An Order compelling Defendant to destroy all misleading and deceptive advertising materials, labels, and unapproved new drugs;
  - E. An Order requiring Defendant to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business act or practice, untrue or misleading advertising, plus pre-and post-judgment interest thereon;
  - F. An award of pre-judgment and post-judgment interest;
  - G. An award of attorney fees and costs;
  - H. Actual and punitive damages of at least \$5 million;
  - I. Such other and further relief as this Court may deem just, equitable or proper.

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Case 3:15-cv-00120-JLB Document 31 Filed 06/19/15 PageID.812 Page 26 of 26 **JURY DEMAND** IX. Plaintiff hereby demands a trial by jury on all issues so triable. Respectfully submitted, Dated: June 19, 2015 /s/ Ronald A. Marron THE LAW OFFICES OF RONALD A. MARRON, APLC RONALD A. MARRON ron@consumersadvocates.com 651 Arroyo Drive San Diego, CA 92103 Phone: (619) 696-9006 Fax: (619) 564-6665 Counsel for Plaintiff and the Proposed Class

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